510(k) SUMMARY
Nidek Non-Contact Tonometer Model NT-4000

1. SUBMITTER INFORMATION

A.	Company Name:	Nidek Incorporated
B.	Company Address:	47651 Westinghouse Drive. Fremont, CA 94539-7474
C.	Company Phone: Company Fax:	(510) 353-7719 (510) 226-5750
D.	Contact Person:	Mr. Hiroshi Okada Regulatory and QA Manager Nidek Incorporated
E.	Date Summary Prepared:	May 16, 2003

2. DEVICE IDENTIFICATION

A.	Classification Name:	Tonometer, AC-Powered
B.	Trade/Proprietary Name:	Nidek Non-Contact Tonometer Model NT-4000
C.	Device Classification:	Class II (per 21 CFR 886.1930)
D.	Product Code:	HKX

3. SUBSTANTIAL EQUIVALENCE

The Nidek Model NT-4000 is of comparable type and is substantially equivalent to the following predicate device:

Predicate Device	Manufacturer	510(k) No.	Date Cleared
Model NT-1000 Non-Contact Tonometer	Nidek Co. Ltd.	K913189	October 15, 1991

4. DEVICE DESCRIPTION

The Nidek Model NT-4000 non-contact tonometer optically detects the momentary state of the cornea (applanated by air pressure) and measures intraocular pressure without touching the cornea.

The Model NT-4000 is comprised of main unit and a measuring unit that are provided on a base unit. Each unit contains the following components:

- MAIN UNIT: A screen, control panel, and joystick are provided on this unit.
- MEASURING UNIT: The air nozzle and photo-detector are provided on this unit.
- BASE UNIT: The chinrest and a printer are provided on this unit.

The Model NT-4000 has the following features:

1. *Auto Alignment Mode*: When the measuring unit approaches the center of the pupil in this mode, the instrument automatically performs alignment in the up, down, left, and right directions, and focuses in the back and forth directions. The measurement then starts automatically.

2. *Automatic Puff Control (APC) Function:* The intraocular pressure measurement can be performed with the air pressure as low as possible. When the measurement range is set to "APC 40" or "APC 60", in the first measurement, the automatic shut-off function (which is to stop puffing air as soon as the light reflected from the cornea is detected) activates in order to eliminate excessive puffing. In the subsequent measurement, the APC function activates to perform the measurement with the minimum air pressure based on the former measurement data. As the patient's eye is protected from excessive air pressure, the patient's comfort level increases and continuous measurement can be performed smoothly.

3. *Pulse Synchronized Intraocular Pressure Measurement:* In addition to the standard IOP measurement mode, the intraocular pressure measurement can be performed in synchronization with an arbitrary position of the pulse signal that is obtained by the detector in the forehead rest. When the signals of the pulse and the completion of the alignment are detected simultaneously, the pulse synchronized IOP measurement is executed. It is possible to select the point of a pulse (i.e., either peak, middle, or bottom) to which measurement will be synchronized.

5. INTENDED USE

The Nidek Model NT-4000 is a non-contact tonometer that is intended for use in the measurement of intraocular pressure of the human eye.

6. TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the Nidek Non-Contact Tonometer Model NT-4000 and the predicate device has been performed, and the results are summarized in the table below. The results of this comparison demonstrate that the Nidek Non-Contact Tonometer Model NT-4000 has the same basic technological characteristics as the predicate device and is equivalent to the marketed predicate device. The differences between the Nidek Non-Contact Tonometer Model NT-4000 and the predicate device are insignificant and do not affect the safety or effectiveness of the device.

PREDICATE DEVICE COMPARISON TABLE		
	Nidek Model NT-4000	**Nidek Model NT-1000 K913189**
Specifications & Characteristics		
Manufacturer	Nidek Co. Ltd. Japan	Nidek Co. Ltd. Japan
Device Name	Non-Contact Tonometer Model NT-4000	Non-Contact Tonometer Model NT-1000
Indications For Use	The Nidek Model NT-4000 is a non-contact tonometer that is indicated for use in the measurement of intraocular pressure of the human eye.	NT-1000 allows one to measure the intraocular pressure by blowing air on the cornea without touching directly to the patient's eye.
MEASUREMENT		
Measurement Range	1 to 60 mmHg	1 to 60 mmHg
Measurement Range Setting	APC40 APC60 40 60	APC30 APC60 30 60
Working Distance	11 mm	11 mm
Automatic Puff Control (APC) Feature	Yes	Yes
Pulse Synchronized IOP Measurement Function	Yes	No
Eyelid Detection Function	Yes	No

PREDICATE DEVICE COMPARISON TABLE		
	Nidek Model NT-4000	**Nidek Model NT-1000 K913189**
ALIGNMENT		
Alignment Method	1 alignment spot & focusing indicator	1 alignment spot & focusing indicator
Inner Fixation Light	Green LED	Green LED
Automatic Movement System	Yes: Horizontal & vertical directions; back & forth directions; Pulse Synchronous system (selection)	No; manual operation only
Alignment Mode	• F.AUTO: auto alignment, auto focus, auto air puff). • S.AUTO: auto alignment, manual focus, auto air puff). • MANUAL: manual alignment, manual focus, auto air puff).	• AUTO: auto alignment, manual focus, auto air puff. • MANUAL: manual alignment, manual focus, auto air puff.
Operation Range by Joystick	36 mm back & forth; 86 mm right & left; 28 mm up & down	36 mm back & forth; 86 mm right & left; 28 mm up & down
DISPLAY / PRINTING		
Screen	5 inch TFT color display	5 inch black & white display
Printer	Thermal line printer	Built-in thermal printer
POWER SPECIFICATIONS		
Voltage	AC 100 / 120 / 230 V	AC 100 / 120 / 220 / 240 V
Frequencies	50 / 60 Hz	50 / 60 Hz
Power Consumption	70VA maximum	80VA maximum
DIMENSIONS & WEIGHT		
Dimensions (W x D x H) & Weight	260 mm (W) x 487 mm (D) x 457 mm (H); approx. 17 kg	260 mm (W) x 487 mm (D) x 440 mm (H); approx. 20 kg

7. PERFORMANCE DATA

The following testing was performed on the Nidek Non-Contact Tonometer Model NT-4000 to demonstrate that it meets all specified requirements and is equivalent to the predicate device:

A. Electrical Safety Testing & Electromagnetic Compatibility

The Nidek Non-Contact Tonometer Model NT-4000 was tested in accordance with EN 60601-1 and EN 60601-1-2, and was found to meet all requirements of both standards.

B. Programmable Electrical Medical Systems

The Nidek Non-Contact Tonometer Model NT-4000 was tested in accordance with EN 60601-1-4 and was found to meet all requirements of the standard.

C. Test Requirements and Test Methods for Ophthalmic Instruments

The Nidek Non-Contact Tonometer Model NT-4000 was tested in accordance with ISO 15004 and JIS T7312 and was found to meet all requirements of the standards.

8. CONCLUSIONS

Nidek Incorporated has demonstrated through its evaluation of the Nidek Non-Contact Tonometer Model NT-4000 that the device is equivalent to the predicate device with respect to intended use, technological characteristics, and safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 4 2003

Nidek Incorporated
c/o Ms. Carol L. Patterson
Patterson Consulting Group, Inc.
21911 Erie Lane
Lake Forest, CA 92630

Re: K031733
Trade/Device Name: Tonometer, AC-Powered
Regulation Number: 21 CFR 886.1930
Regulatory Class: Class II
Product Code: HKX
Dated: June 3, 2003
Received: June 9, 2003

Dear Ms. Patterson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K031733 (To Be Assigned By FDA)

Device Trade Name: Nidek Non-Contact Tonometer Model NT-4000

Indications For Use: The Nidek Model NT-4000 is a non-contact tonometer that is indicated for use in the measurement of intraocular pressure of the human eye.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

Denis L. McCarthy

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K031733